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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/679,043	10/04/2000	Erling Sundrehagen	REF/Sundrehagen/127	4723

7590 11/19/2002  
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EXAMINER

COOK, LISA V

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 11/19/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/679,043

Applicant(s)

SUNDREHAGEN ET AL.

Examiner

Lisa V. Cook

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 August 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 and 13-25 is/are pending in the application.
- 4a) Of the above claim(s) 2-8 and 13-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☒ Claim(s) 1-8 and 13-25 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All   b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Amendment Entry*

1. Applicant's response to the office action mailed 26 February 2002 is acknowledged. In amendment-C filed therein the specification and claim 1 were modified.

## OBJECTIONS WITHDRAWN

### *Specification*

2. Applicant's amendments to the disclosure have obviated the following objections:
  - I. The disclosure is withdrawn from objected because of the following informalities:
    - A. Page 1 is not numbered.
    - B. On page 30, example 9 rabbit is misspelled "rabit". Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. The objection is withdrawn.
  - II. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

### **Arrangement of the Specification**

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-References to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
- (e) Background of the Invention.
  1. Field of the Invention.
  2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Brief Summary of the Invention.
- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.
- (i) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.
- (l) Sequence Listing (see 37 CFR 1.821-1.825).

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In the instant application, the Brief Description of the Drawings is on page 27 before the examples. The description should follow the brief summary of the invention. See MPEP 608.01(f). The objection is withdrawn.

III. The use of several trademarks is noted in this application. They should be capitalized wherever they appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks. (For example, luminol on page 23, see page 28 – Abbot, Amersham on page 30, etc). The objection is withdrawn.

#### OBJECTIONS MAINTAINED

##### *Priority*

3. Receipt is acknowledged of papers (Application No. 9820473.8 filed 9/18/98 in GB) submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.
4. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78). The instant application does not contain the required first sentence referencing GB Application no. 9820473 filed 9/18/98. Please add to the specification.

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***Information Disclosure Statement***

5. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or applicant on PTO-1449 has cited the references they have not been considered.
6. The information disclosure statements filed 1/23/01-Paper #4 and 12/5/01-Paper #10, have been considered as to the merits prior to first action.

**NEW GROUNDS OF REJECTION NECESSITATED BY AMENDMENT**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Newly amended claim 1 is directed to the determination of "transcobalamin II cobalamin", however no such compound is identified in the disclosure. Applicant is invited to show support for the term in the instant application.

REJECTIONS MAINTAINED

*Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claim 1 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 1 is vague and indefinite because it is not clear what the assay method will detect. Initially the claim is directed to the determination of “transcobalamin II cobalamin”. However, the term is not found in the disclosure. The claim further recites the measurement of TC II or cobalamin but the claim utilizes TC II or holo-TC II to separate bound fraction from unbound fraction. It is not clear how “cobalamin” will be detected? Several terms appear to be used interchangeably in the claim, which makes the method unclear. One acronym/term should be utilized for consistency. Appropriate correction is required.

B. Claim 1 is vague and indefinite because a “separation step” or “removal step” between apo-forms of TC II and haptocorrin and holo forms of TC II and haptocorrin is not recited. Applicant argues that the instant invention separates apo and holo complexes. See paper #15, page 4, 4<sup>th</sup> paragraph. However, as recited the sample is contacted with an immobilized cobalamin which binds apo-forms of TC II and haptocorrin, then the same sample is subsequently contacted with a specific binding ligand for TC II or holo-TC II.

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It is not clear as to how the assay will allow for the separation of apo-TC II and apo-haptocorrin when both apo forms and holo forms are present in the reactions mixture. The final detector measure TC II or cobalamin but does not distinguish between apo and holo forms, therein all forms present in the mixture will be detected. Please clarify the separation of apo forms wherein only holo forms remain in the mixture for further detection in the instant claims.

#### NEW GROUNDS OF REJECTION NECESSITATED BY AMENDMENT

##### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Morelli et al. (Journal of Laboratory and Clinical Medicine, March 1977, Volume 89, Number 3, pages 645-652) in view of Maggio (Immunoenzyme technique I, CRC press © 1980, pages 186-187).

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Morelli et al. teach an assay method (radioimmunoassay) for determining transcobalamin II (TC II) bound cobalamin or vitamin B<sub>12</sub> (TC II-B<sub>12</sub>). A cell free sample of body fluid (conducted in either pure or crude preparations). Specifically the cells were removed prior to clotting in the samples (see page 646, serum for testing of immunoassay). B<sub>12</sub> was bound to TC-II then subsequently contacted with a specific binding ligand for the complex (TC II-B<sub>12</sub>). Free and bound fractions were collected and utilized to determine the amount of (TC II-B<sub>12</sub>) present in the test sample. See Measurement of total TC II-B<sub>12</sub> independent of immunoassay (page 646) and Final procedure (pages 648-649).

Morelli et al. differ from the instant invention in not specifically teaching the detection utilizing immobilized reagents.

However, Maggio disclose enzyme immunoassays wherein either the antigen or antibody is immobilized onto a solid phase. The solid phase can be particles, cellulose, polyacrylamide, agarose, discs, tubes, beads, or micro plates (micro titer plates). See page 186.

Morelli et al. and Maggio are analogous art because they are from the same field of endeavor, both inventions teach methods immunoassay methods.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to immobilized reagents on a solid phase substance as taught by Maggio in the assay method to detection transcobalamin of Morelli et al. because Maggio taught that micro plates or micro titer plates for immobilizing reagents "are very convenient to wash thereby reducing labor in assay procedures". Page 186, last line.



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***Response to Arguments***

Applicant contends that the reference of Morelli et al. is not specific for only the holo-TCII content. However applicant's claims are not specific for only the holo-TCII content. The reaction mixture as recited contains both forms (apo and holo) and the final specific binding ligand is directed to TC II or holo-TC II. When TC II is utilized as the ligand with a reaction mixture having both forms it cannot identify only holo-TC. Because the claims read on an assay that does not distinguish the holo forms and Morelli et al. teach one such assay, the rejection is maintained.

10. For reasons aforementioned, no claims are allowed.

***Remarks***

11. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Allen et al.(US Patent #4,332,785) disclose an immunoassay utilizing immunoreactive proteins like transcobalamin II or transcobalamin II receptor to measure reticulocytes.( Abstract)

B. Herbert (US Patent #4,680,273) discloses assay methods to measure B12 deficiency.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 308-4242, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (703) 305-0808. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



*Lisa V. Cook*

*CM1-7B17*

*(703) 305-0808*

*11/12/02*



CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP ~~1800~~ 1641